Remarks

In response to the Office Action, Applicants submit the following:

Drawings

In the office action, the Examiner objects to the drawings. In particular, Figure 1A is objected to for implying that it depicts a table of structures, and no structures are presented. Figure 4 is objected to for allegedly missing a label on the y-axis.

In response, Applicants herein submit a replacement Figure 1 in which reference to "A Is table of structures" is omitted. In addition, a replacement Figure 4 is attached hereto in which the y-axis is properly labeled as "Percentage of binding to DC." Support for the same can be found on page 59, lines 25-28 of the specification.

Accordingly, Applicants respectfully request that the objection to the drawings be reconsidered in light of the above, and withdrawn.

Sequence Listing

According to the Examiner, the application contains sequence disclosures on page 78 and in Figures 19 and 44, and no sequence listing has been provided. In response, Applicants submit an initial sequence listing as attached hereto. A copy of the same is provided on disk as well. The contents of the paper and disk copies are identical. No new matter has been added. Entry of the initial sequence listing is hereby respectfully requested.

The specification and figures have been amended/replaced to include the required sequence identifiers. No new matter has been added.

Objections to Claims 55 and 63

Claims 55 and 63 have been objected to due to informalities. In response, Applicants have cancelled claims 55 and 63. Therefore, the objections have been rendered moot.

Rejections under §112, first paragraph

Claims 53-57, 63-64 and 66 have been rejected under §112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, the specification does not sufficiently describe the claimed genus of glycoconjugates comprising a fucose residue or at least one end-standing N-acetylglucosamine or a "derivative" thereof, or a glycoconjugate comprising a "part, derivative and/or analogue" of a Lewis bloodgroup antigen.

The Examiner asserts that the specification does not disclose a single species or derivative or analogue, or provide a teaching regarding how the structure of the derivatives/analogues correlate with the claimed function of binding to C-type lectin receptors.

In response, Applicants have cancelled claims 53-57, 63-64 and 66 and added new claims 68-76. The new claims more clearly define the invention, and are more specific concerning the glycoconjugate. According to the new claims, the glycoconjugate

must contain at least one Lewis x antigen. Support for this amendment can be found, for example, on page 15, line 16 and page 20, line 28 of the specification.

Accordingly, Applicants respectfully request the above rejection under §112, first paragraph be reconsidered and withdrawn.

Claims 53-54, 56-57, 63-64 and 66 have been rejected under §112, first paragraph as allegedly lacking possession of the claimed invention at the time the application was filed.

Specifically, the Examiner asserts that the specification lacks support for:

- A method comprising providing an antigen presenting cell with a glycoconjugate that has been provided with a fucose residue or N-acetylglucosamine or derivative "and/or" multimer thereof. According to the Examiner, the specification does not support a fucose residue or N-acetylglucosamine or derivative "and/or" multimer thereof. It appears that only support for a fucose residue or N-acetylglucosamine or derivative or multimer thereof is understood by the Examiner.

- A method comprising providing an antigen comprising a glycoconjugate, wherein the antigen is an "antigen of a pathogen." According to the Examiner, the specification discloses that the antigen may comprise a tumor antigen, only.

- A method wherein the antigen "lacks a fucose residue or an end standing N-acetylglucosamine" prior to providing said antigen therewith. According to the Examiner, the specification discloses a tumor antigen lacking a fucose residue or an end standing N-acetylglucosamine – not any antigen.

- A method of augmenting or inducing an effective immune response comprising providing an antigen presenting cell with a ligand comprising an antigen and a glycoconjugate. According to the Examiner, the specification discloses an *in vivo* method of inducing an immune response in an individual. The Examiner asserts that the claims as written cover an *in vitro* method as well as *in vivo* method.

Finally, the Examiner rejects the claims under §112, first paragraph, as allegedly lacking enablement with regards to the recitation of "...a derivative of a fucose residue..." According to the Examiner, the specification is insufficient to enable one skilled in the art to practice the invention as claimed without undue experimentation because no specific examples of derivatives of fucose residues are disclosed.

In response, Applicants have cancelled claims 53-57, 63-64 and 66 and added new claims 68-76. As stated above, the new claims more clearly define the invention, and are more specific concerning the glycoconjugate, and the antigen. According to the new claims, the glycoconjugate must contain at least one Lewis x antigen. The language relating to a "derivative and/or analogue" does not appear in the new claims. The method of the new claims comprises administrating the antigen, which implies an *in vivo* method.

Applicants assert that the method of the invention is not restricted to tumor antigens. On page 9, lines 11 to 14, Applicants state that "the antigen may be derived from any source as long as it (the antigen) is capable of being presented through major histocompatability complex 1, complex II or C1b." Emphasis added. In a preferred embodiment, the antigen comprises a tumor antigen.

In light of the amendments to the claims, and the arguments set forth above, Applicants respectfully request that the §112, first paragraph, rejections be reconsidered and withdrawn.

Rejections under §102

Claims 53-57, 63-64 and 66 have been rejected under §102 as being anticipated by U.S. Patent No. 7,285,642 and its corresponding PCT application WO 00/63251. (Hereinafter collectively referred to as "the `642 patent").

According to the Examiner, the `642 patent discloses a method for increasing an immune response in an animal comprising presenting an antigen to dendritic cells in a form that can bind to a C-type lectin receptor. The Examiner goes on to assert that the `642 patent discloses the use of an antigen conjugated to a compound that can bind to the C-type lectin receptor, and that the compound can be a fucose carbohydrate. The Examiner then states that Lewis blood group antigens comprise a fucose residue, therefore, the fucose carbohydrate taught by the `642 patent can be considered a C-type lectin binding "part, derivative, or analogue" of a Lewis bloodgroup antigen.

In response, Applicants submit that the new claims are free from the language "part, derivative, or analogue" in connection with the Lewis blood group antigen or C-type lectin part thereof. The `642 patent does not disclose the use of a Lewis x antigen.

Accordingly, in light of the amendments to the claims, and the arguments set forth above, Applicants respectfully request that the §102 rejection based on the `642 patent (and its PCT counterpart) be reconsidered and withdrawn.

Claims 53-57, 63-64 and 66 have been rejected under §102(b) as being anticipated by Sabbatini et al., Int. J. Canc. Vol 87. According to the Examiner, Sabbatini et al. teach a method for stimulating an immune response in a patient to treat cancer by administering an antigen (KLH) that has been conjugated to Le^y pentasaccharide. The Examiner asserts that Sabbatini et al. also teach that the antigen conjugate is a tumor antigen, and that KLH lacks a fucose residue. Therefore, the Examiner contends that the antigen Le^y conjugate would inherently result in the antigen being provided to DC-SIGN on antigen presenting cells in the patient. Applicants respectfully disagree.

Sabbatini et al. is concerned with eliciting an immune response against Lewis "y" antigen. The present invention is directed towards stimulating an immune response in an individual wherein a Lewis "x" antigen is used. The Lewis "x" antigen has an entirely different function in the present invention in that it enhances a cellular immune response to the protein part of the glycoconguate. In stark contrast, the method of Sabbatini at el. provides a humoral response that is directed towards the carbohydrate Lewis "y" component of the glycoconjugate. Sabbatini et al. do not anticipate the present claims.

Accordingly, Applicants respectfully request that the §102 rejection based on Sabbatini et al. be reconsidered and withdrawn.

Claims 53-57, 63-64 and 66 have been rejected under §102(b) as being anticipated by WO 98/43677 ("WO '677"). According to the Examiner, WO '677 discloses a conjugate comprising a carbohydrate and a peptide antigen that can be administered to induce anti-tumor immunity and treat cancer. The Examiner goes on to assert that WO '677 discloses that the carbohydrate may be the Le^y antigen (which comprises a fucose residue), and that the peptide antigen can be a tumor peptide or tumor

antigen (i.e. lacking a fucose residue). Therefore, the Examiner contends that the antigen Le^y conjugate would inherently result in the antigen being provided to DC-SIGN on antigen presenting cells in the patient.

In response, Applicants point out that WO '677 is concerned with eliciting a humoral immune response against carbohydrate structures, but is silent concerning Lewis x antigens. WO '677 does not anticipate the present claims.

Accordingly, Applicants respectfully request that the §102 rejection based on WO '677 be reconsidered and withdrawn.

Rejections under the judicially created doctrine of double patenting

Claims 53-57, 63-64 and 66 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, 9, and 15 of U.S. Patent No. 7,285,642.

In response, Applicants submit that new claims 67-76 are patentable over claims 1, 4-7, 9 and 15 of U.S. Patent No. 7,285,642. Accordingly, Applicants respectfully request that the rejection based on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-7, 9, and 15 of U.S. Patent No. 7,285,642 be reconsidered and withdrawn.

It is now believed that this application is in condition for allowance. If the Examiner believes that resolution of any remaining issues can be handled via telephone, she is cordially invited to contact Applicants' Attorney at the telephone number listed below.

Respectfully submitted,

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